J-08-3

Microbial Commercial Activity Notice

40 C.F.R. § 725.155

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to the

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Chemical Control Division
New Chemicals Notice Management Branch

TS Number: TS-KP39SA

Company Sanitized

Date of Submission: July 9, 2008

Submitter: [redacted]

Submitted to: TSCA Document Processing Center (7407)
Room L-100
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

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Certification of Information

I certify that to the best of my knowledge and belief: The company named in this submission intends to manufacture, import, or process for a commercial purpose, other than in small quantities solely for research and development, the microorganism identified in this submission. All information provided in the submission is complete and truthful as of the date of this submission. I am including with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by 40 C.F.R. § 725.160 or § 725.260.

[redacted]

[redacted]

[redacted]

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Substantiation of Confidentiality

The following information is submitted in accordance with 40 C.F.R. § 725.94. Proposed generic names are provided for the microorganism identity in Section 1.4 of the Microbial Commercial Activity Notice (MCAN) pursuant to 40 C.F.R. §§ 725.80(a)(1) and 725.85(a)(3)(ii). A proposed category of use and a generic use description is provided in Section 1.5 of the MCAN pursuant to §§ 725.80(a)(2) and 725.88(b).

A. The nature of the Company's business is relatively unique in U.S. and international commerce. The technology is such that a competitor would be able to discern the production of the microorganism if **Submitter Identity, Microorganism Identity, Process Information, Use, and Internal Company Documents (excluding health and safety studies)** are publicly disclosed. A competitor, upon discovering this information, would have much less of an investment in research and development before being free to manufacture and sell or use the microorganism to our company's detriment. Such a disclosure is intolerable.

B. **This information should be held confidential indefinitely**, *i.e.*, until this technology is obsolete, or until the microorganism is widely known as a result of competing research.

C. Our company has securely guarded information related to **Submitter Identity, Microorganism Identity, Process Information, Use, and Internal Company Documents (excluding health and safety studies)** so that the commercial utility of this information cannot be discovered by others. Only those with a need to know have access to this information.

D. Our company has disclosed information in these areas to outside legal counsel who appropriately protects its confidential status. Only those within [redacted] with a need-to-know are aware of the association between the organisms and their location of manufacture and production. [redacted] securely guards the location of manufacture and production so that its commercial utility cannot be discovered. No confidential information or licenses under the existing patent have been disclosed or granted to others without secrecy agreements.

E. There is no advertising or promotional materials for the microorganisms. Material Data Safety Sheet(s) that will be publicly available will not divulge the changes introduced into the strain. No trade publications reference the microorganisms. The Company's development of the microorganism has been held strictly confidential such that no competitor is aware that this microorganism is in use. No Federal, local, or state agency or court has public files disclosing the Company's identity, process, or referenced internal documents in connection with the microorganisms.

F. The Company, pursuant to 40 C.F.R. § 725.92(b) and § 725.95(e), claims as confidential references to microorganism identity and information that would facilitate the discovery

of its identity in: (1) health and safety studies conducted by the submitter; and (2) published scientific journal articles submitted with the MCAN. Disclosure of microorganism identity would disclose confidential process and manufacture information that is unrelated to health and the environment. Disclosure of identity would reveal the nature of the modifications. Such disclosure would allow competitors to devote less resources to research and development because they would be able to more easily discern the modifications and commercial use. Furthermore, such disclosure would give competitors an advantage in knowing how to create the modifications without a commensurate investment in the research and development. Disclosure of these types of information would give competitors direct knowledge without any effort on their part. Less specific identity information is sufficient to interpret the references provided, because the results and conclusions of the researcher are fully disclosed by the articles.

G. No Federal agency or court has ruled on the confidentiality of the microorganism.

H. Disclosure of this information would allow competitors to devote less resources to research and development because they would be able to easily discern the microorganism and its commercial use. Furthermore, such disclosure would give competitors an advantage in knowing how to create the microorganism without the necessity of undergoing research and development to determine how best to create the microorganism. Disclosure would impart knowledge without any effort on their part.

I. EPA disclosure of the information claimed as confidential would allow a competitor to enter the market more easily. Competitors have the facility, personnel and expertise to produce the microorganisms quickly. This would significantly reduce the research and development time of competitors to create the microorganisms.

J. The microorganism does not leave the site of production or testing in a form which is accessible to the public or its competitors. The cost to a competitor, in time and money, to develop appropriate use conditions would be approximately three to five years and several million dollars. Confidentiality protection and secure handling impede product analysis by others.

[redacted]

[redacted]

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[redacted]

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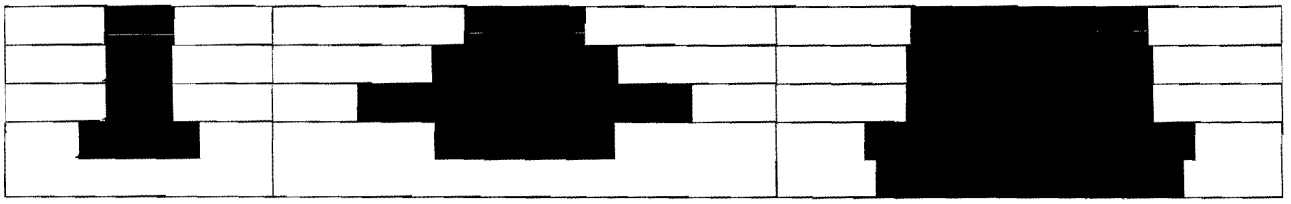
[redacted]



[redacted]

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[redacted]	[redacted]	[redacted]

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2.3.2 Survival, Dissemination and Genetic Transfer[5]

2.3.2.1 Survival and Dissemination

The survival and fate of the MCAN organism can be assessed through an evaluation of the ability of the recipient organism [redacted] to survive outside of controlled laboratory conditions. [redacted] strain has poor growth when outside the laboratory setting [redacted] The inserted genes do not confer any survival advantage to the MCAN organism when compared to the wild-type strain. Therefore, it is not expected that the MCAN organism would survive better than the wild-type strain outside the laboratory.

[redacted] Since the inserted genes do not enhance MCAN organism's ability to [redacted] the MCAN organism can be considered to not pose a harm to animals or the environment.

Dissemination in the environment is expected to be low due to its [redacted] low anticipated environmental release (All designed fermentations are contained in sterile fermentors and cultures are immediately inactivated at the end of fermentation), poor survival capability, worker protection measures, and because the microorganism will only be present at [redacted]

[redacted] demonstrated that the frequency of transfer was 10^{-9} events and lower. Attachment G. The difference between [redacted] gene had any effect on the ability of [redacted] Therefore, it is expected that [redacted] From this data it would be reasonable to conclude that if genetic transfer would occur from the MCAN microorganism, it would be at a low rate that would be reasonably considered as biologically insignificant.

[5] EPA's "Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms" was consulted in order to ensure submitter addresses points deemed important to EPA.

[redacted]

[redacted]

2.3.2.3 Detection

Detection in the environment can be achieved through standard microbiological techniques for [redacted] The sensitivity limit of detection for this technique is sufficient for detection of the MCAN microorganism in the environment.

[redacted]

2.3.3.2 Toxicology

[redacted] cannot survive outside a laboratory setting Therefore, the MCAN organism can be considered safe for the intended use.

2.3.3.3 Interaction and Toxicology Due to Modifications

[redacted] No pathogenicity or toxicity effects are expected from the presence of these genes, or their products. [redacted] reduces its growth capability and further diminishes its ability to survive in the environment.

[redacted]

2.3.4 Involvement in Biogeochemical or Biological Cycling Processes[7]

[7] EPA's "Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms" was consulted in order to ensure submitter addresses points deemed important to EPA.

The presence of [redacted] organism, and the presence [redacted] in the environment, is not anticipated to have an adverse effect on the indigenous flora or fauna. As discussed above, the MCAN microorganism does not appear to have an advantage for growth or survival. Furthermore, the metabolite from the MCAN microorganism [redacted] No other effects are anticipated. As a result, the MCAN microorganism is not anticipated to have an adverse effect on biogeochemical or biological cycling processes or in rate limiting steps in mineral or nutrient cycling or involvement in inorganic compounds cycling such as sequestration or transformation of heavy metals.

3.0 Byproducts

In accordance with 40 C.F.R. § 725.155(e) the following information is provided.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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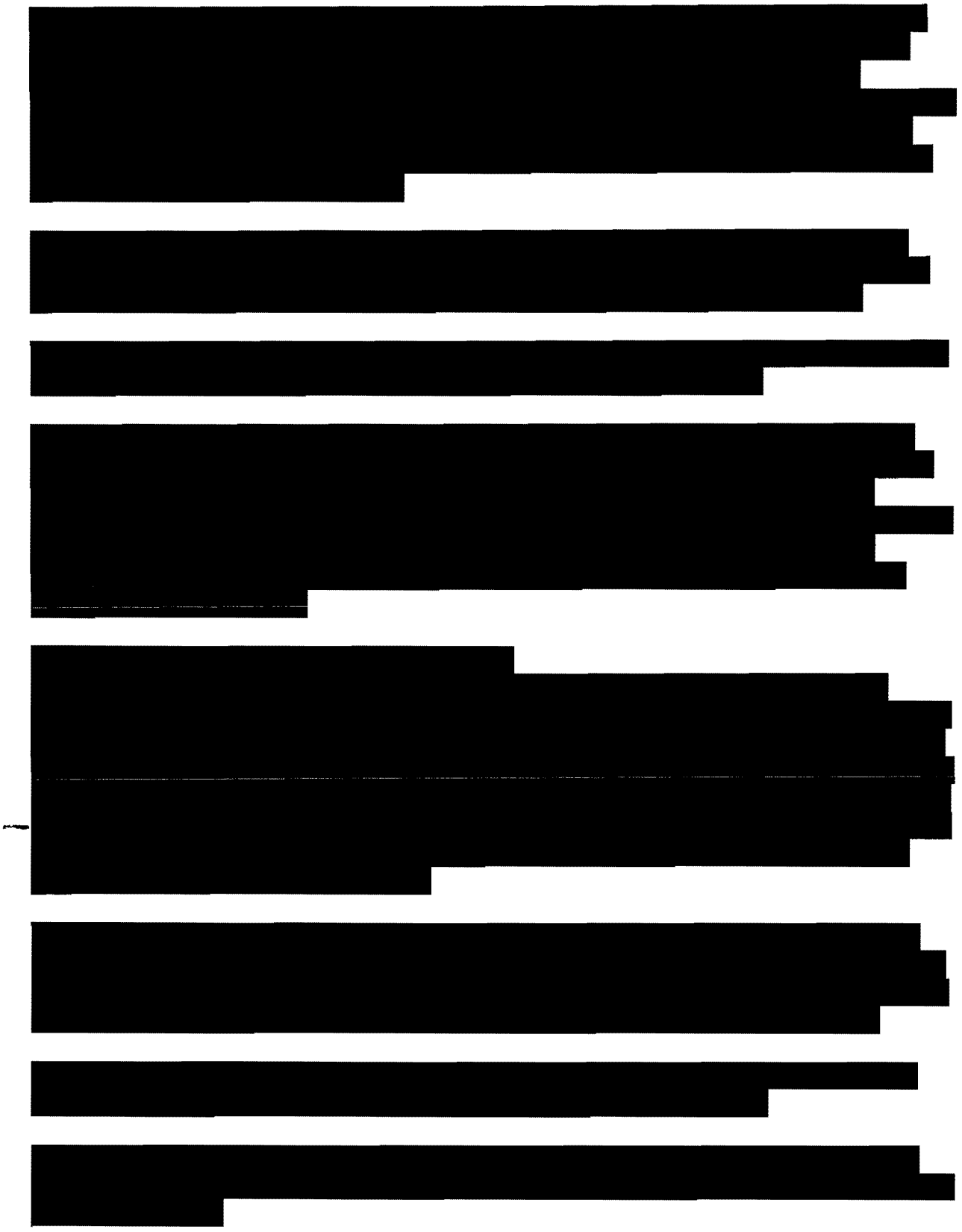

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8.0 Health and Safety Data

As required by 40 C.F.R. §725.160, existing data regarding the health and environmental effects of the microorganism are reported in this submission and copies of the studies and references in the submitter's possession and control are provided.

[redacted]

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Pages 30 through 189

Removed as Confidential